AMENDMENTS TO THE CLAIMS

Please cancel claim 48 without prejudice or admission, and amend claim 42 as follows:

Claim 1 (Previously presented): A method for producing virus inactivated human gammaglobulin G, which method comprises:

(a) suspending a precipitate of human gammaglobulin G in an aqueous solution containing a carbohydrate;

(b) reducing the content of contaminants in the suspension with PEG;

(c) applying the suspension to an anionic exchange resin in column to obtain an effluent;

(d) subjecting the effluent to ultrafiltration so that the content of PEG in said effluent is reduced;

(e) viral inactivation of the filtered effluent by at least one method selected from the group consisting of (i) Pasteurizing and (ii) treating with solvent/detergent; and

(f) precipitating and washing the virus inactivated human gammaglobulin G from the viral inactivated effluent.

Claim 2 (Previously presented): A method for producing virus inactivated human gammaglobulin G according to claim 1, wherein the precipitate of human gammaglobulin G is obtained or provided by fractionation of human plasma with ethanol.

Claim 3 (Previously presented): A method for producing virus inactivated human gammaglobulin G according to claim 2, wherein the precipitate of human gammaglobulin G comprises fractions II+III of the Cohn method.

Claim 4 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 1, wherein the carbohydrate is a sugar-alcohol.

Claim 5 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 4, wherein the sugar-alcohol is sorbitol.

Claim 6 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 4, wherein the sugar-alcohol is present at a concentration of between 2% and 10% (w/v).

Claim 7 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 1, in which the step of reducing the concentration of contaminants in the suspension is performed with PEG at a concentration from 2.5% to 5.5% (w/w) and at a pH from 4.8 to 5.5.

Claim 8 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 1, wherein the pH of the suspension is between 5.7 and 6.3 when applied to the anionic exchange resin column.

Claim 9 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 1, wherein the anionic exchange resin column:

(a) Contains DEAE-agarose resins, and

(b) Admits a charge of between 1 g and 2.5 g of fraction II+III per ml of resins.

Claim 10 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 1, in which the effluent is subjected to ultrafiltration through a membrane of 100 kDa nominal molecular cut-off.

Claim 11 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 10 in which, after said step of ultrafiltration, the effluent is diafiltered against a solution containing a sugar alcohol.

Claim 12 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 11, in which the sugar alcohol is sorbitol.

Claim 13 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 11, in which the sugar alcohol is present in solution at a concentration between 2% and 10% (w/v).

Claim 14 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 11, in which said diafiltration is performed at a pH between 4.0 and 4.8.

Claim 15 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 11, in which said diafiltration is performed with a transmembrane pressure below 1.2 bar.

Claim 16 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 1 further comprising, prior to the step of viral inactivation, a step of treating the filtered effluent at an acid pH.

Claim 17 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 16, wherein said step of treating the filtered effluent at an acid pH is carried out in the presence of a sugar-alcohol at a pH of 3.95 to 4.05 and at a temperature of 35 to 38 °C from 1 to 4 hours.

Claim 18 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 17 in which the sugar-alcohol is sorbitol, said sorbitol being present at a concentration between 2% and 10% (w/v).

Claim 19 (Previously presented): A method for the production of virus-inactivated human gammaglobulin G according to claim 1, wherein viral inactivation comprises Pasteurization of the filtered effluent.

Claim 20 (Previously presented): A method for the production of virus-inactivated human gammaglobulin G according to claim 19 in which the filtered effluent is Pasteurized in the presence of a sugar-alcohol.

Claim 21 (Previously presented): A method for the production of virus-inactivated human gammaglobulin G according to claim 20, wherein the sugar alcohol is sorbitol.

Claim 22 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 20 in which the sugar alcohol is present at a concentration of between 25% and 35% (w/w).

Claim 23 (Previously presented): A method for the production of virus-inactivated human gammaglobulin G according to claim 20 in which the filtered effluent is treated with solvent/detergent after said Pasteurization.

Claim 24 (Previously presented): A method for the production of virus-inactivated human gammaglobulin G according to claim 23 in which, before said treatment with solvent/detergent, the Pasteurized effluent is diluted with water for injection so that:

(a) the concentration of sugar alcohol is 25% (w/w) or less, and

(b) the concentration of protein is between 1% and 3% (w/v).

Claim 25 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 1, wherein viral inactivation comprises treatment with solvent/detergent.

Claim 26 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 25 in which, after treatment with said solvent/detergent, the effluent is diluted with water for injection so that the pH is adjusted to between 7.0 and 9.0.

Claim 27 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 26, wherein the pH is adjusted to between 7.8 and 8.4.

Claim 28 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 26 in which the effluent is diluted by adding, for each kilogram of effluent, between 1-2 kg of water for injection.

Claim 29 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 1 in which the virus inactivated human gammaglobulin G is precipitated from the virus inactivated effluent by the addition of PEG.

Claim 30 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 29 in which PEG is added to the virus inactivated effluent to a final concentration between 12% and 17% (w/w).

Claim 31 (Previously presented): A method for the production of virus-inactivated human gammaglobulin G according to claim 29, in which the precipitated human gammaglobulin G is separated on a tangential flow filtration membrane.

Claim 32 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 31, in which the tangential flow filtration membrane has a pore size from 0.1 to 0.45 microns.

Claim 33 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 31 wherein the precipitate is washed in said tangential flow filtration membrane.

Claim 34 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 33, in which the precipitate is washed by the addition of four or more volumes of solution used to precipitate the virus inactivated human gammaglobulin G.

Claim 35 (Previously presented): A method for the production of virus-inactivated human gammaglobulin G according to claim 29 wherein the precipitated virus inactivated human gammaglobulin G is solubilized by the addition of an acid solution at pH below 5.5, which acid solution contains a carbohydrate.

Claim 36 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 35 wherein the acid solution comprises acetic acid with an adjusted concentration of between 1 mM to 10 mM.

Claim 37 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 35 wherein the carbohydrate comprises a sugar alcohol.

Claim 38 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 37, in which the sugar alcohol is present at a concentration from 5-20% (w/w).

Claim 39 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 35 wherein said acid solution is adjusted with an alkali to pH 4.0-4.5.

Claim 40 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 35, in which the amount of acid solution added is such that the concentration of PEG in the solubilized human gammaglobulin G is from 2% to 4% (w/w).

Claim 41 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 40, in which the concentration of PEG in the solubilized human gammaglobulin G is from 2.8% to 3.4% (w/w).

Claim 42 (Currently amended): A method for the production of virus-inactivated human gammaglobulin G according to claim 35, further comprising steps of:

(a) adding an alkali to the acid solution after solubilization of the human gammaglobulin G, so that the pH is adjusted to between 7.5 and 8.5, and

(b) precipitating and separating insoluble high molecular weight aggregates from the pH adjusted solution.

Claim 43 (Original): A method for the production of virus-inactivated human gammaglobulin G according to claim 42, wherein insoluble high molecular weight aggregates are separated from the pH adjusted solution by filtration.

Claim 44 (Previously presented): A method for the production of virus-inactivated human gammaglobulin G according to claim 42 further comprising, after separating insoluble high molecular weight aggregates from the pH adjusted solution, diafiltering and concentrating of the solution, pH adjusted to 4.0 - 4.8, through ultrafiltration membranes of 100 kDa nominal molecular cut-off and at a transmembrane pressure below 1.2 bar.

Claim 45 (Previously presented): A method for the production of virus-inactivated human gammaglobulin G according to claim 44, wherein the solution is concentrated to a protein concentration of 1% to 3% (w/v) and pH adjusted to 4.4 - 5.0.

Claim 46 (Previously presented): A method for the production of virus-inactivated human gammaglobulin G according to claim 44, further comprising steps of:

(a) heating the solution to 25 ± 5 °C after precipitation of insoluble high molecular weight aggregates; and

(b) nanofiltering of the solution through membranes having a nominal pore size of 50 nm or less.

Claim 47 (Original): A method for producing virus inactivated human gammaglobulin G according to claim 46 wherein the membranes have a nominal pore size of approximately 20 nm.

Claim 48 (Canceled)